

***Interested in this job? Please submit your resume to [Regulatory Director \(Tampa Site\)](#). Please do not call the office regarding this job or for a status update. All qualified candidates will be contacted via phone call and email.***

## **Regulatory Manager**

Clinical Research of West Florida – Tampa, FL

The Regulatory Manager will be responsible for establishing, maintaining, and providing administrative management of all site regulatory documents in accordance with federal regulations, ICH Guidelines, good Clinical Practices CRWF Standard Operating Procedures.\

### **Daily responsibilities include:**

- Conducts all regulatory activities in accordance with Institutional Review Board (IRB) guidelines, Good Documentation Practices (GDPs), Good Clinical Practice (Google Cloud Platform) standards, Standard Operating Procedures (SOP's),
- Generates, facilitates, and maintains all study related regulatory documents from study start up through study close out, ensuring quality, accuracy, and timeliness
- Prepares and maintains study records for archiving and/or retrieval
- Maintains study related documents in the CRWF electronic master file and regulatory binder
- Reviews all regulatory documents prior to Sponsor/Monitor visits
- Provides administrative and operational support to study coordinators, Investigators and other CRWF site staff
- Maintains record of site staff training and ensures protocol specific and internal training is maintained
- Arranges on-site visits for monitors and provides assistance during monitoring visits
- Serves as the CRWF liaison to sponsors, governing agencies and facilitate the transmission of verbal and written communication to pharmaceutical companies, and other research entities as needed.

### **Requirements include:**

- Must be able to manage multiple ongoing projects at a time
- Must be detail oriented and highly organized
- Must be able to work independently
- Must be able to communicate effectively both verbally and in writing
- Historical regulatory experience required